MAY 0 3 2002

K021216

Sterling Medivations, Inc.
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510(k) SUMMARY

Date Submitted: April 16, 2001

Submitter: Sterling Medivations, Inc. 66 Neptune Drive, Groton, CT 06340
Company Phone 650-814-4083, Company Fax 770-242-3178

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-814-4083
Applicant Fax 770-242-3178

Trade Name of Device: Simplicity™ Simplex P Infusion Set for use with the MiniMed Paradigm infusion pumps.
Common Name of Device: Intravascular administration set.
Classification Name: Percutaneous intravascular catheter.

Predicate Device: Sterling Medivations Sterling Medivations Simplicity Simplex Soft Infusion Set, FDA 510 (k) K 020629 and Sterling Medivations Simplicity Soft YP Infusion Set K011187.

Description of the New Device: Sterling Medivations Inc.'s ("SMI") Simplicity™ Simplex P Infusion Set is designed to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe.

The Simplicity Simplex P Infusion Set is designed for use by people with diabetes to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe. It is inserted into the subcutaneous tissue of a patient and the Simplicity YP connector is attached to the medication reservoir. This is substantially equivalent to the predicate device and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from PTFE, (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a Simplicity YP connector consisting of a needle hub and reusable pump adapter and reservoir connector.

The Simplicity Simplex P Infusion Set is an infusion administration set, connecting to the Paradigm reservoir by means of a Simplicity YP connector consisting of a needle hub and reusable pump adapter and reservoir connector and subcutaneously in the patient through an indwelling catheter made of Polytetrafluorthylene (PTFE). The Sterling Medivations Simplicity Simplex P Infusion Set may be used with any paradigm infusion device that delivers continuous or intermittent flow. The connecting tubing is made from a polyethylene tube.

The 25 gauge-indwelling catheter is introduced into the subcutaneous tissue by a removable 27-gauge insertion needle formed from a lumen made of AISI 304 stainless steel. The insertion needle is removed and a connector needle is attached to the hub fixed to the indwelling catheter. This connector needle mates with the indwelling catheter forming a seal that permits the infusion of medication without leakage. The connector needle is made from AISI 304 stainless steel and it is connected to the connecting tubing with a connector housing. The connector tubing proximal end is attached to a Simplicity YP connector consisting of a needle hub and reusable pump adapter and reservoir connector for connection to a MiniMed Paradigm pump and reservoir. The connecting tube is solvent bonded to the connector housing and to the needle hub

connector.

Intended Use of the New Device: The intended use of the Simplicity Simplex P Infusion Set is to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe. The Simplicity Simplex Infusion Set is substantially equivalent to the Sterling Medivations Simplicity Soft YP Infusion Set K011187 and Simplicity Simplex Soft Infusion Set, FDA 510 (k) K 020629.

Comparison of the Technological Features of the New Device and Predicate Device:

The Simplicity Simplex P Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Sterling Medivations Simplicity Soft YP Infusion Set K011187 and Simplicity Simplex Soft Infusion Set, FDA 510 (k) K 020629.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the Sterling Medivations Simplicity Simplex P Infusion.

The differences that exist between the new and predicate device are as follows:

1. The new device proximal end is a Simplicity YP connector consisting of needle hub and reusable pump adapter and reservoir connector used to attach to a MiniMed Paradigm infusion pumps and reservoir in place of a Luer fitting. It is currently used on the Sterling Medivations Simplicity Soft YP Infusion Set K011187 and the Device otherwise similar to the Simplicity Simplex Soft Infusion Set, FDA 510 (k) K 020629.

Performance Data Supporting Substantial Equivalence: To prove substantial equivalence both Simplicity Simplex Infusion Set and Sterling Medivations Simplicity Simplex Infusion Set FDA 510(k) K010373 meet the catheter requirements of:

- CDRH 21 C.F.R. Section 880.5440 Intravascular administration set
- ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements)
- ISO 10555 Sterile, single use intravascular catheters (Part 5: Peripheral Catheters).
- ISO 11135:1994 Medical devices -- Validation and routine control of ethylene oxide sterilization
- ISO 11138-2:1994 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization.
- ISO 9626: 1991 Stainless Steel needle tubing for the manufacture of medical devices.
- ISO 11607: 1997 Packaging for terminally sterilized medical devices.
- ISO 8535: 1991 Sterile single use syringes, with or without needle, for insulin.
- FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end product endotoxin test for human and animal parenteral drugs, biological products, and medical devices.
- ODE Blue Book Memorandum #K90-1.
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing.

And the design process adhered to is the Center for Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed,

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joel Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
66 Neptune Drive
Groton, Connecticut 06340

MAY 0 3 2002

Re: K021216
Trade/Device Name: Simplicity Simplex P Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 16, 2002
Received: April 17, 2002

Dear Mr. Douglas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021216

510(k) Number (if known):

Device Name: Simplicity Simplex P Infusion Set

Indications For Use:

The intended use of the Simplicity Simplex P Infusion Set is to provide a means for infusion and/or injection of fluids into the body below the surface of the skin when attached to a MiniMed Paradigm pump or syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucente
(Divis... ...ection Control,
Dis... ... Devices
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